

FILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10

EV524613681US

Express Mail Label Number

November 14, 2005

Date of Deposit

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

FRANZ HAMMERSCHMID

APPLICATION NO: 10/524,899

FILED: FEBRUARY 17, 2005

FOR: SCREENING ASSAY FOR IDENTIFYING AGENTS THAT
MODULATE PAK KINASE OR CD45 TYROSINE PHOSPHATASE
ACTIVITY

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

LETTER CORRECTING OFFICIAL FILING RECEIPT

Sir:

The official filing receipt received in the above-identified application erroneously lists the Title.
Please issue a corrected filing receipt listing the Title as follows:

-- SCREENING ASSAY FOR IDENTIFYING AGENTS THAT MODULATE PAK KINASE OR
CD45 TYROSINE PHOSPHATASE ACTIVITY --

A copy of the filing receipt with the correction noted is enclosed. Also enclosed is a copy of the first page of the International Search Report showing wherein the text of the title was changed to the above-listed title by the European Patent Office.

No fee is believed to be required by this request for a corrected filing receipt.

Respectfully submitted,

Novartis
Corporate Intellectual Property
One Health Plaza, Building 104
East Hanover, NJ 07936-1080
(862) 778-2614
Date: 4/16/05



Gregory C. Houghton
Attorney for Applicant
Reg. No. 47,666



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPL NO.	FILING OR 371 (c) DATE	ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	DRAWINGS	TOT CLMS	IND CLMS
10/524,899	02/17/2005	1645	1500	PD/4-32578A		9	6

CONFIRMATION NO. 8422

001095
NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

FILING RECEIPT



OC000000017044654

GCH

Date Mailed: 10/07/2005

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please mail to the Commissioner for Patents P.O. Box 1450 Alexandria Va 22313-1450. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

Applicant(s)

Franz Hammerschmid, Vienna, AUSTRIA;

Power of Attorney: The patent practitioners associated with Customer Number 001095.

Domestic Priority data as claimed by applicant

This application is a 371 of PCT/EP03/10048 09/10/2003
which claims benefit of 60/409,732 09/11/2002
and claims benefit of 60/409,733 09/11/2002

Foreign Applications

UNITED KINGDOM 0300591.5 01/10/2003
UNITED KINGDOM 0300590.7 01/10/2003



Projected Publication Date: To Be Determined - pending completion of Security Review

Non-Publication Request: No

Early Publication Request: No

Title

Preliminary Class
435

Screening assay for Identifying Agents that Modulate p42^{src} Kinase
or CD45 tyrosine phosphatase activity

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at <http://www.uspto.gov/web/offices/pac/doc/general/index.html>.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, <http://www.stopfakes.gov>. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

LICENSE FOR FOREIGN FILING UNDER Title 35, United States Code, Section 184 Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR

1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 4-32578A/612/NFI	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/EP 03/10048	International filing date (day/month/year) 10/09/2003	(Earliest) Priority Date (day/month/year) 11/09/2002
Applicant NOVARTIS AG		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 7 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international search was carried out on the basis of the sequence listing :

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☐ Certain claims were found unsearchable (See Box I).

3. ☒ Unity of invention is lacking (see Box II).

4. With regard to the title,

☐ the text is approved as submitted by the applicant.

☒ the text has been established by this Authority to read as follows:

SCREENING ASSAY FOR IDENTIFYING AGENTS THAT MODULATE PAK KINASE OR CD45 TYROSINE PHOSPHATASE ACTIVITY

5. With regard to the abstract,

☐ the text is approved as submitted by the applicant.

☒ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the drawings to be published with the abstract is Figure No.

☐ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

☒ None of the figures.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/EP 03/10048

Box III TEXT OF THE ABSTRACT (Continuation of item 5 of the first sheet)

Screening assays for identifying an agent that modulates the activity of a phosphate catalyzing enzyme, i.e., a PAK Kinase or a CD45 tyrosine Kinase, comprising the following steps:

- a) providing a phosphate catalyzing enzyme,
- b) providing a peptide,
- c) optionally providing a phosphate containing donor,
- d) providing a candidate compound,
- e) contacting the enzyme of step a) with a peptide of step b) and optionally the phosphate containing donor of step c) in the absence of d) and in the presence of d) for a predetermined period of time so that an enzymatic product can be formed,
- f) transferring at least an aliquot of the enzymatic product formed in step e) to a solid phase which is capable to bind to the peptide in the enzymatic product,
- g) detecting the enzymatic product bound to the solid phase,
- h) determining whether there is a difference in the amount of enzymatic product in the absence and in the presence of a candidate compound in step e), and
- i) choosing an agent that modulated the activity of an enzyme, which method is characterized in that
 - I) the enzyme is a PAK kinase,
 - the peptide comprises the amino acid sequence S-S-L-R-A-S-T,
 - the phosphate containing donor of step c) is present in step e), and
 - the enzymatic product detected in step g) is the amount of phosphoserine and/or phosphothreonine in the bound peptide; OR
 - II) the enzyme is CD45 tyrosine phosphatase,
 - the peptide comprises the amino acid sequence R-N-Q-E-T-Y-E-T-L-K-H or A-E-N-T-I-T-Y-S-L-L-M-H-P, wherein Y is phosphorylated tyrosine,
 - the phosphate containing donor of step c) is absent in step e), and
 - the enzymatic product detected in step g) is the amount of phosphotyrosine in the bound peptide.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/EP 03/10048

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 C12Q1/42 C12Q1/48

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 C12Q C07K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, MEDLINE, BIOSIS, COMPENDEX, INSPEC, PAJ, EMBASE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 01/25477 A (CAMBRIDGE DRUG DISCOVERY LTD; FREARSON JULIE ANN (GB)) 12 April 2001 (2001-04-12) claims 1-18 ----- <i>Van Eyk et al.</i>	1-4, 6-9
Y	US 6 248 549 B1 (QUEEN'S UNIVERSITY AT KINGSTON) 19 June 2001 (2001-06-19) column 24, line 57 - column 25, line 5; claims 1-8 ----- <i>Van Eyk et al.</i>	1-4, 6-9
Y	US 2002/045564 A1 (COTE GRAHAM P ET AL) 18 April 2002 (2002-04-18) page 2, paragraph 14 - page 6, paragraph 91 ----- -/--	1-4, 6-9



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *G* document member of the same patent family

Date of the actual completion of the international search

24 June 2004

Date of mailing of the international search report

01.09.2004

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Stachowiak, O

INTERNATIONAL SEARCH REPORT

International Application No

PCT/EP 03/10048

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6 040 149 A (KOLESNICK RICHARD N ET AL) 21 March 2000 (2000-03-21) column 59; claims 1-3; figures 1-21; example 7 ----- <i>Traugh et al</i>	1-4,6-9
Y	US 6 228 989 B1 (TUAZON POLYGENA T ET AL) 8 May 2001 (2001-05-08) column 9, line 36 - column 10, line 31 -----	1-4,6-9
A	WO 99/29894 A (EPPS DENNIS E ;UPJOHN CO (US); MARSCHKE CHARLES K (US)) 17 June 1999 (1999-06-17) the whole document -----	
A	EP 1 184 665 A (MEDICAL & BIOLOG LAB CO LTD) 6 March 2002 (2002-03-06) claims 4-20 -----	1-4,6-9
P,X	CA 2 387 406 A (SMITHKLINE BEECHAM CORP) 30 November 2002 (2002-11-30) abstract; claims 1-59 -----	1-4,6-9

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/EP 03/10048

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 0125477	A	12-04-2001	AU 7537400 A WO 0125477 A2	10-05-2001 12-04-2001
US 6248549	B1	19-06-2001	US 6227658 B1 US 2002045564 A1 JP 2000079356 A CA 2241389 A1	08-05-2001 18-04-2002 21-03-2000 23-12-1998
US 2002045564	A1	18-04-2002	US 6248549 B1 CA 2241389 A1 JP 2000079356 A US 6227658 B1	19-06-2001 23-12-1998 21-03-2000 08-05-2001
US 6040149	A	21-03-2000	NONE	
US 6228989	B1	08-05-2001	US 2003088057 A1	08-05-2003
WO 9929894	A	17-06-1999	AT 233325 T AU 738194 B2 AU 1703499 A CA 2306686 A1 DE 69811724 D1 DE 69811724 T2 DK 1036192 T3 EP 1036192 A1 ES 2192801 T3 JP 2001526380 T PT 1036192 T SI 1036192 T1 WO 9929894 A1 US 6203994 B1 US 2003235865 A1 US 2001044117 A1	15-03-2003 13-09-2001 28-06-1999 17-06-1999 03-04-2003 16-10-2003 10-06-2003 20-09-2000 16-10-2003 18-12-2001 30-06-2003 31-08-2003 17-06-1999 20-03-2001 25-12-2003 22-11-2001
EP 1184665	A	06-03-2002	JP 2000325086 A EP 1184665 A1 WO 0072011 A1	28-11-2000 06-03-2002 30-11-2000
CA 2387406	A	30-11-2002	CA 2387406 A1 EP 1361285 A2 JP 2003047499 A US 2003113711 A1	30-11-2002 12-11-2003 18-02-2003 19-06-2003

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP 03/10048

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

see annex

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-2 (all partly), 3-4, 6-9 (all completely)

Methods, kits and uses for identifying an agent that modulates the activity of a PAK kinase, wherein the substrate peptide comprises the sequence 'SSLRAST'.

2. claims: 1-2 (all partly), 5 (completely)

Methods and kits for identifying an agent that modulates the activity of a CD 45 tyrosine phosphatase, wherein the substrate peptide comprises the sequence 'RNQETYETLKH' or 'AENTITYSLLMHP'.
